K122489(1/1)

DEC 10 2012

510(k) Summary

NAME OF FIRM:	Emerge Medical 720 S. Colorado Blvd. Suite 550-S Denver, CO 80246
DATE PREPARED:	November 29, 2012
510(K) CONTACT:	Victoria Trafka Vice President of Engineering & Quality Tel: (303) 225-7909
PROPOSED TRADE NAME:	Emerge Medical Solid Bone Screws
DEVICE CLASSIFICATION:	Class II; 21 CFR 888.3040
CLASSIFICATION NAME:	Smooth or threaded metallic bone fixation fastener
PRODUCT CODE:	HWC
DEVICE DESCRIPTION:	The Emerge Medical Bone Fixation screws consist of cancellous, cortical and shaft screws with washers, as needed, in a variety of sizes to accommodate differing anatomic requirements. The screws are provided non-sterile.
INDICATIONS FOR USE:	The Emerge Medical Solid Bone Screws are intended to provide bone fixation in the management of osteotomies, fusions, and fractures of metaphysis and diaphysis of both small and large bones and the pelvis. The screws may be used alone or with washers.
MATERIALS:	Titanium alloy (ASTM F136) Stainless steel (ASTM F138)
PREDICATE DEVICES:	Synthes K112583 and K061621
TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characteristics, including the intended use, material, general design, and sizes of the device are the equivalent the predicate devices.
PERFORMANCE DATA:	Static tests performed according to ASTM 543 demonstrated that the device performs as well as or better than the predicate devices. Testing included screw variations in material, diameters, lengths, partial versus full threads, and drive types. Clinical data were not needed to demonstrate substantial equivalence for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter dated: December 10, 2012

Emerge Medical
% Ms. Victoria Trafka
Vice President of Engineering & Quality
720 South Colorado Boulevard, Suite 550-S
Denver, Colorado 80246

Re: K122489
Trade/Device Name: Emerge Medical Solid Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 13, 2012
Received: November 14, 2012

Dear Ms. Trafka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122489(1/1)

Indications for Use Statement

510(k) Number (if known): _____

Device Name: **Emerge Medical Solid Bone Screws**

Indications for Use:

The Emerge Solid Bone Screws are intended to provide bone fixation in the management of osteotomies, fusions, and fractures of metaphysis and diaphysis of both small and large bones and the pelvis. The screws may be used alone or with washers.

Prescription Use _____X_____ or Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi
for (Division Sign-Off)
Division of Orthopedic Devices

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